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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,095

01/27/2004

Woonza M. Rhee

2500-2287.08

3196

23980

7590

05/25/2006

EXAMINER

ROGERS, JAMES WILLIAM

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C  
1400 PAGE MILL ROAD  
PALO ALTO, CA 94304-1124

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/766,095

Applicant(s)

RHEE ET AL.

Examiner

James W. Rogers

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/12/2005</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,10-14,17-18,21-26,28-32 are rejected under 35 U.S.C. 102(b) as being unpatentable by Rhee et al. (US 5,308,889).

Rhee teaches dehydrated collagen-polymer strings and the methods to produce them, in which the strings can produce woven or knitted materials including blood vessel grafts and vascular stents. See abstract and col 4 lin 35-68. The collagen is crosslinked to the polymer by its own bonds (lysine side chains, amino groups and hydroxyl groups) or by linking groups; the non-collagen polymer includes polyethylene glycol bis-succinimidyl ester. See col 6 lin 42-col 7 lin 35, lin 49-56, lin 57-63, col 8 lin 9-13, lin 49-52, col 14 lin 25-col 20 lin 41. Rhee also discloses methods to crosslink the collagen-polymer matrix in buffered aqueous solution with a pH of 7.4, the concentration of either the 1<sup>st</sup> or 2<sup>nd</sup> component can be in molar excess and the amount formed upon admixture are within the ranges specified by applicant. See examples.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1618

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee et al. (US 5,308,889) in view of Weissleder et al. US (5,514,379).

The Rhee patent is disclosed above. Rhee is silent on the exact types of amines on the collagen or linkers but it is obvious that since collagen is comprised of amino acids and the patent states that the side groups are capable of reacting with the synthetic polymer the following amino acids side groups will meet the limitations in claims 15-16 and 19-20 (specifically lysine and proline end units meet the limitation for primary or secondary alkyl amines and cysteine meets the sulfhydryl nucleophile limitation). Regarding claim 27 the limitation that the second crosslinkable component is a solid before addition to the reaction mixture is just an optimization of the experimental conditions to produce the crosslinked polymer, besides Rhee does disclose that SG-PEG (electrophilic 2<sup>nd</sup> component) is in solid form but instead of adding

Art Unit: 1618

it directly to solution with the collagen (nucleophilic 1<sup>st</sup> component) Rhee first diluted the SG-PEG then added to solution, it would have been obvious for the skilled artisan at the time of the invention to add the 2<sup>nd</sup> component to the reaction mixture in dry form.

Rhee does not specifically disclose that the electrophilic groups can be different on crosslinkable component 2.

Weissleder discloses hydrogel compositions including proteins, polylysines and polyethyleneimine (satisfies the limitation of alkyl secondary amines as nucleophiles), crosslinked to polyalkylene oxides with electrophilic groups (including succinimidyl ester and sulfosuccinimidyl ester) the electrophiles can be different or the same organic groups. See abstr, col 4 lin 24-30, col 6 lin 51- col 7 lin 20, col 7 lin 34-col 8 lin 17.

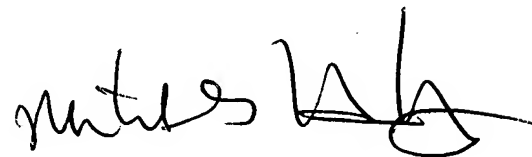
It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Rhee teaches all of applicants claimed invention but is silent on the use of different electrophilic groups on polyalkylene oxides, while the Weissleder patent is primarily used to show that the use of different electrophilic groups attached to polyalkylene oxides was known in the art at the time of the invention. The motivation to combine the above documents would be a dehydrated matrix composition comprising polymers with two or more nucleophilic groups which can be the same or different, crosslinked to polymers containing two or more electrophilic groups which can be the same or different. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Michael G. Hartley", with a stylized flourish at the end.

MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER